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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK, by ANDREW M. CUOMO, Attorney General of the State of New York, and THE CITY OF NEW YORK,	No. 07 Civ. 8434 (GBD)
Plaintiffs,	
- against -	
MERCK & CO., INC.,	
Defendant.	

PLAINTIFFS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF MOTION TO REMAND FOR LACK OF FEDERAL SUBJECT MATTER JURISDICTION

PRELIMINARY STATEMENT

In its Notice of Removal and its opposition to plaintiff's motion to remand, Merck has failed to carry its burden of demonstrating federal subject matter jurisdiction over this case, and the case must be remanded to the state court in which it was filed. Most notably, Merck has not established federal question jurisdiction over plaintiffs' exclusively state and local law claims because it fails to answer one simple question: *what specific question of federal law must be resolved in order to determine liability under plaintiffs' six state and local causes of action?*

Merck asserted in its Notice of Removal that removal jurisdiction exists under the standards the Supreme Court articulated in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314-15 (2005). Plaintiffs demonstrated in their moving papers that Merck failed to meet those standards because: (a) Merck could not identify *any* specific issues of federal law that would have to be decided in order to resolve plaintiffs' state and local law claims; (b) Merck could not identify any such issues that were actually disputed and substantial to this case; and (c) Merck could not overcome the clear congressional intent (as determined by the Supreme Court) that cases such as this one be heard by state courts.

Merck's arguments in opposition to this motion lack merit and this case must be remanded to the New York State court for at least the following reasons:

First, Merck's efforts to diminish its burden of establishing jurisdiction are contrary to established Supreme Court and other law, and must be disregarded. *See* Point I, *infra*.

Second, Merck still cannot point to *any specific* issues of federal law that must necessarily be resolved in order for liability to be determined under plaintiffs' claims. *See* Point II, *infra*.

Third, Merck similarly cannot point to any issues of federal law that are actually disputed and substantial and that Congress intended to be heard in federal court. *See* Point III, *infra*.

Fourth, the overwhelming authority rejects the arguments Merck makes, and Merck's effort to distinguish some, but not all, of those authorities is without merit. *See* Point IV, *infra*.[1]

ARGUMENT

I. MERCK CANNOT DIMINISH ITS HEAVY BURDEN OF ESTABLISHING REMOVAL JURISDICTION

Merck does not deny in its opposition that it bears the heavy burden of establishing federal subject matter jurisdiction. (*See* Supreme Court and Second Circuit cases cited at Plaintiffs' Memorandum of Law in Support of Their Motion to Remand for Lack of Federal Subject Matter Jurisdiction ("Pl. Mem.") at 4.) Instead, it argues that it satisfied its burden by making only general assertions in its Notice of Removal. It denounces as a "red herring" plaintiffs' argument that more is required. (Opp. Mem. at 14.)

Merck was required to provide a short, plain statement establishing this Court's removal jurisdiction. *See Allman v. W.H. Hanley*, 302 F.2d 559, 562 (5th Cir. 1962). Under the *Grable* standards invoked by Merck in removing this case, however, Merck was required to provide more than general statements. To satisfy those standards, Merck was required to establish that (a) plaintiffs' state law claims necessarily give rise to questions of federal law that (b) are actually disputed by the parties and substantial, and (c) can appropriately be determined by a federal court in accordance with the congressional intent as to the division of responsibilities between state and federal courts. *Grable*, 545 U.S. at 314. This standard leaves no room for arguments that rely on general references to federal laws that might somehow be implicated by

[1] Merck's first argument in its opposition is an effort to avoid remand at this time by seeking a stay. (*See* Defendant Merck & Co., Inc.'s Opposition to Plaintiffs' Motion to Remand for Lack of Federal Subject Matter Jurisdiction ("Opp. Mem.") at 1-5.) As plaintiffs have shown in their opposition to Merck's separate stay motion and in its opening memorandum on this remand motion, remand can be easily decided without delay and further waste of the parties' and the judiciary's resources.

plaintiffs' claims. Rather, Merck had to point to specific claims by plaintiffs and how they purportedly raise specific federal issues that require resolution. It did not do so.

II. MERCK HAS AGAIN FAILED TO IDENTIFY ANY SPECIFIC FEDERAL ISSUES THAT MUST BE RESOLVED

In their opening memorandum, plaintiffs described the facts and holdings in *Grable* and other decisions by the Supreme Court, the Second Circuit and other courts that address when federal question jurisdiction will apply to exclusively state law claims because they depend upon resolution of actually disputed and substantial federal questions. (*See* Pl. Mem. at 7-13.) In its opposition, Merck does not question that description of the applicable standards. Instead, it argues that it has met those standards by referring generally to the Food, Drug & Cosmetics Act and federal Medicaid laws.

Missing from Merck's argument is any linking of plaintiffs' actual causes of action to the provisions of the FDCA and Medicaid laws that Merck references. In fact, Merck does not even mention plaintiffs' causes of action. By failing to link any of plaintiffs' claims to the FDCA or federal Medicaid law, Merck cannot meet the very first of the *Grable* standards – it cannot establish that liability under plaintiffs' six state and local causes of action can be determined only by first resolving issues of federal law.

Moreover, Merck has not identified any specific questions under the FDCA or federal Medicaid law that must be resolved in this case. Merck leaves entirely unanswered important questions: Must plaintiffs prove that Merck violated federal law in order to establish liability on their claims? What elements of plaintiffs' claims can only be established by proving violations of federal law? What provisions of federal law must be shown to be violated? Because Merck could not answer these questions, it cannot begin to meet the *Grable* standards.

Plaintiffs assert six causes of action under four state and local statutes -- the New York State False Claims Act, the New York City False Claims Act, the New York Executive Law and the New York Social Services Law. They will demonstrate Merck's violations by showing that Merck engaged in a campaign of misinformation and concealment about the cardiovascular risks of its pain medication Vioxx. As plaintiffs described in their complaint, for example, Merck armed its thousands of sales representatives with misleading "obstacle responses" to overcome the "obstacles" to Vioxx sales created by information that cast doubt on the safety of Vioxx. (*See* Complaint ¶¶ 34-53.)[2] These sales representatives were charged with the task of allaying doctors' concerns about these cardiovascular concerns, and thus increasing prescriptions even to patients with a established coronary artery disease. (*Id*.) Merck has not pointed to any issues of federal law that must be decided to find such liability.

In its opposition, Merck makes reference to federal food and drug law and federal Medicaid law, but none of the provisions cited has any bearing on the claims plaintiffs have asserted. (Opp. Mem. at 7-9, 11-12.) *First*, Merck argues that federal food and drug law is implicated because it "comprehensively regulates" aspects of prescription drug marketing. (*Id*. at 7, 11.) It points out that the FDA is charged with approving and monitoring drugs and is involved in regulating labels and package inserts that accompany the drugs. (*Id*.) These facts, however, are not at issue here. Merck may well have misled the FDA about Vioxx, but regardless of that fact, plaintiffs can establish liability by demonstrating that Merck (and its sales representatives) misled physicians about Vioxx.

Merck's argument appears to be that *Grable* provides for removal jurisdiction where a plaintiff's claims are somehow related to an area where there is "comprehensive" federal

[2] A copy of the Complaint is attached as part of Exhibit A to the previously submitted Declaration of Randall M. Fox, dated October 26, 2007 ("Fox Decl.").

regulation. Nothing in the Supreme Court's *Grable* decision supports that notion. To the contrary, the Supreme Court found removal jurisdiction is warranted only where the state law claims cannot be decided without first resolving questions of federal law, those questions are actually disputed and substantial to the case and the congressional intent was to allow federal courts to hear such cases. *See Grable*, 545 U.S. at 314. By confirming the validity of *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804, 813 (1986), the *Grable* Court recognized that the existence of federal regulation, and regulation under the FDCA in particular, is not alone a basis for removal under the standards the Court articulated. *Grable*, 545 U.S. at 318. In *Merrell Dow*, the plaintiff alleged that a drug manufacturer misbranded a drug "because its labeling did not provide adequate warning that its use was potentially dangerous" and that this "violation of the FDCA 'in the promotion' of Bendectin 'constitutes a rebuttable presumption of negligence.'" *Merrell Dow*, 478 U.S. at 805-06. Merck's argument must thus actually be that federal law preempts plaintiffs' claims, but any assertion of that new argument for removal jurisdiction is untimely and precluded. *See* 28 U.S.C. § 1446 (requiring a statement of the grounds for removal within 30-days of receipt of initial pleadings).[3]

Second, Merck points to certain provisions in federal Medicaid law. According to Merck, plaintiffs' claims "depend[] on the interpretation and application of federal statutory provisions that govern what drugs must be covered by or can be excluded from all state Medicaid drug reimbursement programs" (Opp. Mem. at 8), and "the Court will need to determine whether New

[3] Moreover, Merck has already lost the preemption argument in the multidistrict proceedings against it, where Judge Fallon denied Merck's motion for summary judgment that was premised on a statement by the FDA as to its own authority in a preamble to a regulation, which preamble was not subject to usual rulemaking procedures and was contrary to the FDA's historical position about its own authority. *See In re Vioxx Products Liability Litig.*, 501 F. Supp. 2d 776, 786-87 (E.D. La. 2007). Merck cites to the preamble at note 3 of its Opposition Memorandum, but fails to inform this Court that its argument has already been rejected in the multidistrict proceeding.

York was required to include Vioxx on its Medicaid formulary." (Opp. Mem. at 11-12.) Any review of the complaint will show that plaintiffs' claims are not about whether Vioxx should have been included in or excluded from Medicaid reimbursement or New York's formulary. Plaintiffs are seeking to recover Medicaid and consumer funds that were spent on Vioxx as a result of Merck's fraud and concealment. In particular, they are seeking recovery of funds spent to provide Vioxx to those patients who would not have received the drug had Merck not engaged in its campaign of diminishing the cardiovascular risks of Vioxx – patients with established coronary artery disease. Even Merck does not argue that the State and City are required to pay public funds for prescriptions obtained by fraud.[4]

III. MERCK FAILS TO IDENTIFY FEDERAL ISSUES THAT ARE ACTUALLY DISPUTED, SUBSTANTIAL AND APPROPRIATE FOR RESOLUTION BY A FEDERAL COURT

Grable and its line of cases require more than just the existence of federal questions that must be decided to resolve state law claims. They also require that such questions be actually disputed, substantial and appropriate for resolution in a federal court as a matter of federalism and comity. *See Von Essen v. C.R. Bard, Inc.*, No. CV 07-1850ML, 2007 U.S. Dist. LEXIS 82298, at *13 (D. R.I. Nov. 6, 2007) ("The fact that fraud-on-the-FDA is a necessary element of the [plaintiffs'] claim only shows that the claim indeed includes a federal issue. The Supreme Court has not 'treated "federal issue" as a password opening federal courts to any state action embracing a point of federal law.'" (quoting *Grable*, 545 U.S. at 314)). Here, the Court need not reach this question because Merck failed to identify specific issues of federal law that must necessarily be decided to resolve plaintiffs' claims. Even if Merck had identified such issues,

[4] Merck also does not contradict the established case law that the fact that state Medicaid programs receive some funding from the federal government does not give rise to federal subject matter jurisdiction. (*See* Pl. Mem. at 19 n.7.)

however, it has not established that there are any questions that are actually disputed or substantial to resolving this dispute. Merck could not do so because plaintiffs' claims can be resolved without having to determine whether Merck misled the FDA or what criteria are necessary for including a drug within the Medicaid program.

Notably, Merck has entirely failed to address in its opposition the clear evidence that Congress intended that claims such as plaintiffs' be heard in state court. (*See* Pl. Mem. at 18-20.) As plaintiffs described in their opening memorandum and above, the Supreme Court in *Grable* recognized and let stand the holding in *Merrell Dow* that state law claims for negligence in mislabeling a prescription drug that implicated the FDCA did not give rise to federal question jurisdiction because Congress clearly intended for state courts to handle such claims. (Pl. Mem. at 7-8.) Plaintiffs further described Congress' intent by referring to Congress' empowering states to recover Medicaid funds obtained by fraud, and its encouragement of states to establish their own bodies to recover such funds and to enact their own False Claims Act, which can also be used to recover such funds. (*Id*. at 18-20.) Plaintiffs further described New York's great interest in recovering Medicaid funds, for the Medicaid program is the State's largest budget item, accounting for approximately $48 billion. (*Id*. at 20.) Merck has no response.

IV. MERCK IS UNABLE TO DISTINGUISH THE OVERWHELMING NUMBER OF CASES THAT REJECT ITS ARGUMENTS

In their opening memorandum, plaintiffs cited more than a dozen cases that have rejected the very argument that Merck makes here. (Pl. Mem. at 10-13.) In its opposition, Merck tries to distinguish only some of them, and its grounds for distinction are far from convincing. (Opp. Mem. at 15-18.) Merck does not address numerous cases at all. Among them are cases brought against pharmaceutical manufacturers by states seeking to recover Medicaid funds because the manufacturers improperly marketed the drugs. *See Utah v. Eli Lilly & Co*., No. 2:07-CV-380

TS, 2007 U.S. Dist. LEXIS 65571 (D. Utah Sept. 4, 2007); *South Carolina v. Eli Lilly & Co.*, No. 7:07-18750HMH, 2007 U.S. Dist. LEXIS 56847 (D. S.C. Aug. 3, 2007); *South Carolina v. Jannsen Pharmaceutica, Inc.*, No.6:07-1452-HMH, 2007 U.S. Dist. LEXIS 49904, at *5 (D.S.C. July 10, 2007); *Pennsylvania v. Eli Lilly & Co.*, No. 07-1083, 2007 U.S. Dist. LEXIS 46946 (E.D. Pa. June 26, 2007); *Alaska v. Eli Lilly & Co.*, No. 3:06-cv-88 TMB, 2006 U.S. Dist. LEXIS 52783 (D. Alaska July 28, 2006). In each of these cases, the defendant argued removal jurisdiction under *Grable*, contending that plaintiffs' claims purportedly implicated the FDCA and federal Medicaid law. In each case, the court granted remand because it rejected those arguments and found that the state law claims did not give rise to federal question jurisdiction.[5]

Merck did attempt, unpersuasively, to distinguish the remand motions granted against it in a Vioxx case brought by an attorney general. (*See* Opp. Mem. at 17; *see also Texas v. Merck*, 385 F. Supp. 2d 604 (W.D. Tex. 2005) & No. A-06-CA-232-LY Slip Op. (W.D. Tex. May 10, 2006)).[6] Merck's primary argument is that the federal court in Texas should not have reached the merits of the remand motion.[7] That argument has no bearing on the validity of the decisions. As a secondary argument, Merck asserts that the Texas court "ignores the intricate statutory and regulatory schemes inherent in FDCA and Medicaid law." (Opp Mem. at 17.) It is Merck, however, that ignores that the Texas court addressed that argument and rejected it. *See* Slip Op. at 5-6.

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[5] In its motion to stay, Merck argues that all actions by states are essentially the same. (*See* Memorandum of Law in Support of Merck's Motion to Stay Proceedings Pending Transfer Decision by the Judicial Panel on Multidistrict Litigation at 2-4.) Despite the inaccuracy of that characterization, Merck should not be heard pragmatically to argue otherwise on this motion.

[6] A copy of the slip opinion is attached as Exhibit B to the Fox Decl.

[7] Merck is rather cryptic in its argument. It asserts that "As explained in Section I, *supra*, that court's decision to remand is clearly at odds with the majority view." (Opp. Mem. at 17.) "Section I" is Merck's argument for a stay of proceedings.

Merck seeks to distinguish *Caggioano v. Pfizer Inc*., 384 F. Supp. 2d 689 (S.D.N.Y. 2005), because "the Medicaid-related issues that must necessarily be determined to find Merck liable in this action were not at issue there." (Opp. Mem. at 18). Merck ignores that the very same arguments about the FDCA were made and rejected in that case, in which plaintiff alleged that a pharmaceutical manufacturer misled physicians about the safety of its drug.

Merck also attempts to distinguish the set of decisions in cases where states have sought to recover Medicaid funds from pharmaceutical manufacturers based on manipulation of the "Average Wholesale Price." (Opp. Mem. at 16-17.) According to Merck, those cases are different because the purported federal question at issue was limited. (*Id*.) Merck neglects that federal jurisdiction did not apply to those cases even though they involved Medicaid funds and prescription drugs subject to the "comprehensive regulation" of the FDA, and even though the claims asserted there were explicitly premised on a question that the defendants claimed was about federal law (while Merck is claiming here (wrongly) that plaintiffs' claims only *implicitly* are premised on federal law).[8]

In its Notice of Removal, Merck ignored the overwhelming precedent against its arguments and relied on two cases, *In re Zyprexa Prods. Liab. Litig*., 375 F. Supp. 2d 170, 172 (E.D.N.Y. 2005), and *County of Santa Clara v. Astra USA, Inc*., 401 F. Supp. 2d 1022 (N.D. Cal. 2005). As plaintiffs explained in their opening memorandum, these cases are factually distinct from the present action in that the claims there were directly and explicitly premised upon questions of federal law, and, moreover, they depart from the standards set forth in *Grable* and the numerous other authorities plaintiffs have described. (Pl. Mem. at 16-17). Merck does

[8] Merck also tries to distinguish some of the Average Wholesale Price cases on the additional ground that the courts in three of them also found procedural deficiencies in the removal petitions. (Opp. Mem. at 17.) The presence of alternative holdings, however, did not affect the holdings that no federal jurisdiction existed.

not deny that the claims in those cases specifically involved federal law standards. In its Opposition Memorandum, Merck nevertheless points to these same cases. It also cites *West Virginia v. Eli Lilly & Co.*, 476 F. Supp. 2d 230 (E.D.N.Y. 2007) (Opp. Mem. at 6). That case, however, was decided by the same judge and in the same multidistrict proceeding as the *In re Zyprexa* decision. It adds nothing to the prior decision and does not overcome Merck's failure to satisfy the *Grable* standards, nor the large body of precedent that refused to apply the *Grable* standards to find removal jurisdiction to cases analogous to this one.[9]

CONCLUSION

For all the foregoing reasons, the State and City respectfully request that this Court remand this case to the New York State Supreme Court for the County of New York.

Dated: New York, New York
November 16, 2007

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[9] That body of precedent continues to grow. *See Greene v. Novartis Pharmaceuticals Corp.*, No. 7:07-CV-00091-HL, 2007 U.S. Dist. LEXIS 84082, at **13-15 (M.D. Ga. Nov. 14, 2007) (no removal jurisdiction where plaintiff's state law claims asserted that drug manufacturer inadequately tested a prescription drug and made false representations about its safety); *Ekas v. Burris*, No. 07-61156-CIV-MARRA, 2007 U.S. Dist. LEXIS 84340, at *12 (S.D. Fl. Nov. 14, 2007) (in case about backdating stock options, there was no removal jurisdiction under *Grable* because "the fact that some of [the] false statements were made to the SEC and may have violated federal law is tangential to proving the breach of fiduciary duty"); *Von Essen*, 2007 U.S. Dist. LEXIS 82298, at *12, *supra*.

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PROOF OF SERVICE

Randall M. Fox hereby declares under penalty of perjury that: I am a Special Assistant Attorney General in the Office of the Attorney General of the State of New York, counsel for plaintiff The People of the State of New York, and that I caused a copy of Plaintiffs' Reply Memorandum of Law in Further Support of Their Motion to Remand for Lack of Federal Subject Matter Jurisdiction, to be served upon counsel for defendant Merck & Co., Inc. by causing the same to be hand delivered on November 16, 2007 addressed to:

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